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Bimekizumab 2-Year Impact on HS Symptoms by Baseline Draining Tunnel Count: Data from BE HEARD EXT

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Objective

We report how HS-specific patient-reported symptoms improve with BKZ treatment over time stratified by baseline DT count.

Background

- Hidradenitis suppurativa (HS) is characterized by recurrent formation of lesions, including abscesses and draining tunnels (DTs) (fistulas/sinus tracts), that are often painful, pruriginous, and exude a malodorous discharge.[1]
- HS has a substantial negative effect on patients' quality of life.[1]
- Bimekizumab (BKZ), is a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17F in addition to IL-17A.[2]

Methods

- Data were pooled from the BE HEARD I&II studies and the open-label extension, BE HEARD EXT.[3,4] Week 48 BE HEARD I&II completers could enroll in BE HEARD EXT and receive open-label BKZ 320 mg every 2 weeks (Q2W) or BKZ every 4 weeks (Q4W) based on ≥90% HS Clinical Response (HiSCR90; averaged from BE HEARD I&II Weeks 36, 40, and 44) (**Figure 1**).
- Data are reported for patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT (BKZ Total).
- Number of baseline DTs were grouped as 0, 1–2, 3–5, or >5.
- Here, we report proportion of patients in severity categories ('none' to 'very severe') for each item (skin pain, smell or odor, drainage or oozing, and itch) in the HS Symptom Questionnaire (HSSQ) based on item scores over 2 years.
- Data are reported using observed case (OC).

Results

- At baseline, 1,014 patients were randomized. Among the 657 BE HEARD I&II Week 48 completers who entered BE HEARD EXT, 556 patients received continuous BKZ from baseline. Patients were categorized approximately equally into each baseline DT group (**Table 1**).
- With BKZ treatment, the proportion of patients with none/mild skin pain increased over 2 years, regardless of DT count at baseline (**Figure 2**).
- With BKZ treatment, the proportion of patients with none/mild smell or odor increased over 2 years, irrespective of DT count at baseline (**Figure 3**).
- Over 2 years, the proportion of patients with none/mild drainage or oozing generally increased following BKZ treatment, irrespective of baseline DT count (**Figure 4**).
- Over 2 years, the proportion of patients reporting none/mild itch increased with BKZ treatment, irrespective of baseline DT count (**Figure 5**).

Conclusions

Patients with a higher number of DTs at baseline rated their individual symptoms (skin pain, drainage or oozing, smell or odor, and itch) as more severe.

The proportion of patients achieving no/mild symptoms increased after 2 years of treatment with bimekizumab.

With bimekizumab treatment, patient reported symptoms related to HS lesions improved over 2 years regardless of baseline DT count, with an increase in the proportion of patients achieving no/mild symptoms across each individual HS symptom after 2 years.

Plain Language Summary

Why was this study needed?
Hidradenitis suppurativa (HS) is a long-term skin disease. The sores, known as lesions, that patients have can smell, itch, drain pus, and cause pain. Patients can have many or few lesions. Studies were conducted to evaluate if the drug, bimekizumab, could help treat the symptoms of patients with moderate to severe HS.

What did this study show?
Bimekizumab can help treat the symptoms caused by HS lesions, regardless of the number of lesions. Patients saw their pain, smell, pus, and itch symptoms get better.

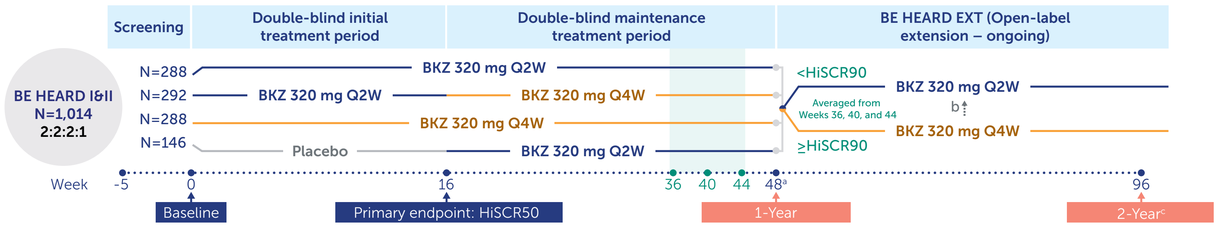
Why is this important?
It is important to make sure that new drugs for HS work well in treating the symptoms of HS.

Table 1 Baseline characteristics

	BKZ Total N=556
Age (years), mean ± SD	36.3 ± 12.2
Sex, female, n (%)	299 (53.8)
Racial group, n (%)	
White	448 (80.6)
Black or African American	55 (9.9)
BMI (kg/m²), mean ± SD	32.5 ± 7.8
Smoking status, current, n (%)	260 (46.8)
Duration of HS (years), mean ± SD	7.4 ± 7.1
AN count, mean ± SD	16.9 ± 18.5
DT count, mean ± SD	3.8 ± 4.3
Hurley stage, n (%)	
II	303 (54.5)
III	253 (45.5)
DLQI total score, mean ± SD	11.0 ± 6.8
HiSQOL total score, mean ± SD	24.6 ± 12.8
Prior biologic use,[a] n (%)	112 (20.1)
Baseline antibiotic use, n (%)	54 (9.7)
DT count at baseline, n (%)	
0	131 (23.6)
1–2	149 (26.8)
3–5	147 (26.4)
>5	129 (23.2)

OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (n=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. OC, n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly. **[a]** Patients received prior biologic therapy for any indication.

Figure 1 Study design



Among 657 BE HEARD I&II completers who entered BE HEARD EXT, 556 patients received BKZ from baseline. **[a]** Patients who completed Week 48 of BE HEARD I&II could enroll in BE HEARD EXT and receive open-label BKZ Q2W or BKZ Q4W based on HiSCR90 responder status using the average lesion counts from Week 36, Week 40, and Week 44 of BE HEARD I&II; **[b]** In the first 48 weeks of the ongoing BE HEARD EXT, dose adjustment from BKZ Q4W to BKZ Q2W was permitted based on prespecified criteria for reduction in improvement from baseline in AN count; **[c]** Cumulative 2-year data (48 weeks in BE HEARD I&II and 48 weeks in BE HEARD EXT).

Figure 2 HSSQ Skin Pain by DT Count at Baseline (OC)

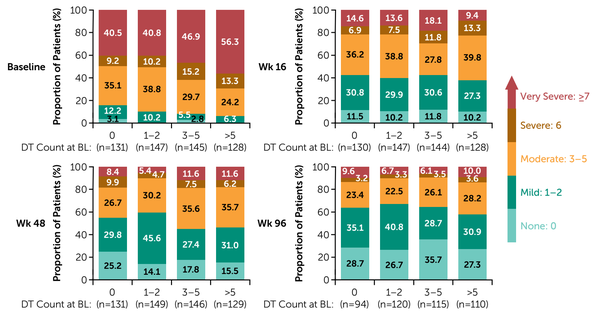
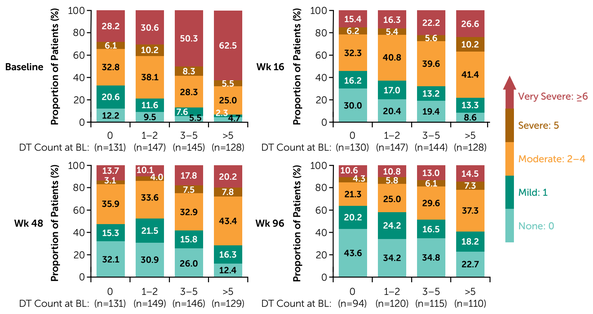


Figure 3 HSSQ Smell/Odor by DT Count at Baseline (OC)



OLE set; only included patients who entered BE HEARD EXT at Week 48. BKZ Total (n=556) comprised patients randomized to BKZ from baseline in BE HEARD I&II who entered BE HEARD EXT and continued to receive BKZ. HSSQ assesses patients' perception of symptoms over the past 7 days. HSSQ scores are reported for BKZ Total. DT count at baseline are categorized as follows: 0 (N=131), 1–2 (N=149), 3–5 (N=147), and >5 (N=129). OC, n/N: denominator represents number of patients with a non-missing lesion count assessment in the given week, and percentages are calculated accordingly.

Figure 4 HSSQ Drainage/Oozing by DT Count at Baseline (OC)

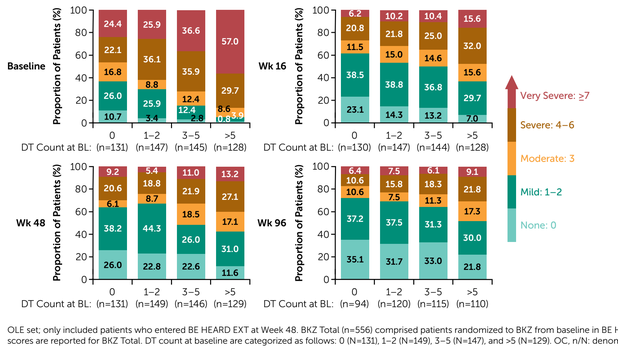
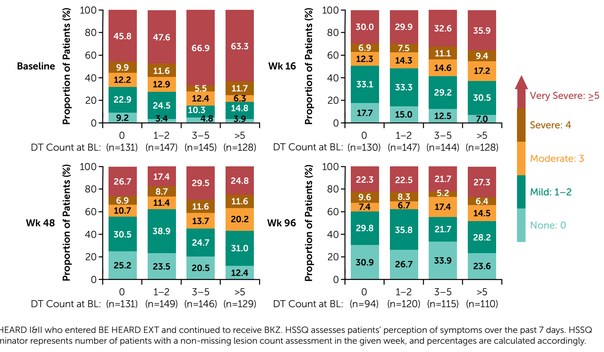


Figure 5 HSSQ Itch by DT Count at Baseline (OC)



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Abbreviations: AN: abscess and inflammatory nodule; **BKZ:** bimekizumab; **BL:** baseline; **BMI:** body mass index; **DLQI:** Dermatology Life Quality Index; **DT:** draining tunnel; **HiSCR50/90:** ≥50%/90% reduction from baseline in the total AN count with no increase from baseline in abscess or draining tunnel count; **HS:** hidradenitis suppurativa; **HiSQOL:** Hidradenitis Suppurativa Quality of Life; **HSSQ:** HS Symptom Questionnaire; **Ig:** immunoglobulin; **IL:** interleukin; **OC:** observed case; **PBO:** placebo; **Q2W:** every two weeks; **Q4W:** every four weeks; **SD:** standard deviation; **Wk:** Week.

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References: 1. Zouboulis CC et al. JEADV 2015 29, 619–44; 2. Glatt S et al. JAMA Dermatol 2021;157: 1279–88; 3. Kimball AB et al. Lancet. 2024;403:2504–19 (NCT04242446, NCT04242498); 4. BE HEARD EXT: www.clinicaltrials.gov/study/NCT04901195. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **CJS**, **MLP**, **IH**, **KRVS**, **AP**, **ZR**, **NH**, **RR**, **JL**, **IP**, **RW**, **AK**, **TT**; Drafting of the publication, or revising it critically for important intellectual content: **CJS**, **MLP**, **IH**, **KRVS**, **AP**, **ZR**, **NH**, **RR**, **JL**, **IP**, **RW**, **AK**, **TT**; Final approval of the publication: **CJS**, **MLP**, **IH**, **KRVS**, **AP**, **ZR**, **NH**, **RR**, **JL**, **IP**, **RW**, **AK**, **TT**. **Author Disclosures: CJS:** Investigator for AbbVie, ChemoCentryx, Incyte, InflaRx, Novartis and UCB; consultancy fees from AbbVie, Alumis, AstraZeneca, InflaRx, Incyte, Logical Images, Sonoma Biotherapeutics and UCB; speaker for AbbVie and Novartis. **MP:** Consultant and investigator for Abbvie, Eli Lilly and Company, Incyte, Janssen, MoonLake Immunotherapeutics, Novartis, Pfizer, Prometheus, Sanofi, Sonoma Biotherapeutics, and UCB; consultant for Alumis, FIDE, Trifecta Clinical, and Zura Bio; investigator for Bayer, Bristol Myers Squibb, and OASIS Pharmaceuticals; received royalities from Beth Israel Deaconess Medical Center. **IH:** Consultant for AbbVie, Avita, Boehringer Ingelheim, Galderma, Incyte, Janssen, Novartis, Pfizer, Sonoma, UCB, and Union Therapeutics; investigator for Avita, Incyte, Lenicura, L'Oréal/La Roche-Posay, and Pfizer; board member and past-president of the HS Foundation and Global Vitiligo Foundation. **KRVS:** Consultancy/honoraria from Boehringer Ingelheim, Novartis, and UCB. **AP:** Investigator and/or speaker and/or advisor for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Celgene, Eli Lilly, Galderma, GSK, Hexal, Janssen, LEO Pharma, MC2 Therapeutics, Medac, Merck Serono, Mitsubishi Pharma, MSD, MoonLake Immunotherapeutics, Novartis, Pfizer, Regeneron, Roche, Sandoz, Schering-Plough, Tigercat Pharma, and UCB. **ZR:** Investigator, speaker, and/or advisor for AbbVie, Almirall, Amgen, Avene, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Celltrion, CeraVe, Eli Lilly and Company, Janssen, La Roche Posay, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, and UCB; personal fees for attending meetings or for travel from AbbVie, Almirall, Janssen, Novartis, UCB, and Sanofi. **NH:** Investigator and speaker for AbbVie, Maruho, and Sun Pharma. **RR, JL, IP, AK:** Employee and shareholder of UCB. **RW:** Veramed statistical consultant for UCB. **TT:** Consultancy/advisory boards/speaker fees from Abbvie, Boehringer Ingelheim, Novartis and UCB; treasurer of the European Hidradenitis Suppurativa Foundation e.V. **Acknowledgments:** These studies were funded by UCB. We thank the patients and their caregivers in addition to the investigators and their teams who contributed to these studies. The authors acknowledge Susanne Wiegratz, MSc, UCB, Monheim, Germany for publication coordination, Kate Metcalfe, BSc, Costello Medical, London, UK, for medical writing and editorial assistance, and the Costello Medical Creative Team for design support. All costs associated with development of this poster were funded by UCB.

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